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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,780	06/22/2006	Tomohiro Osanai	4600-0114PUS1	3987
2292 7590 08/08/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER PESELEV, ELLI	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 08/08/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/553,780	Applicant(s) OSANAI, TOMOHIRO	
	Examiner Elli Peshev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

The disclosure is objected to because of the following informalities: the specification on page 1 fails to state that this application is a 371 of PCT/JP04/035598.

Appropriate correction is required.

Claims 3, 6, 11 and 20 are objected to because of the following informalities: the term "erythromaycin" is misspelled. The correct spelling is "erythromycin". Appropriate correction is required.

Claims 1-4 and 8-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting the proliferation of human coronary vascular smooth muscle cells (CASMCs), does not reasonably provide enablement for inhibiting proliferation of smooth muscles, preventing diseases caused by CASMCs and for the prevention of re-obstruction after the operation of obstruction in cardiac coronary artery. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

Claims 1-4, 13-16 and 19-21 read on inhibiting proliferation of vascular smooth muscles.

Claims 8-12 read on preventing diseases caused by the proliferation or growth of vascular smooth muscles.

Claim 17 reads on the method of treating diseases caused by proliferation or growth of vascular smooth muscles.

Claim 18 reads on preventing re-obstruction after the operation of obstruction in cardiac coronary artery.

(B) The state of the prior art.

The inhibition of the proliferation of vascular smooth muscles is not known in the art. What is known in the art is the inhibition of proliferation of vascular smooth muscle cells.

The prevention of diseases caused by the proliferation of growth of vascular smooth muscle cells is not known in the art.

Total prevention of re-obstruction is also not known in the art.

(C) The amount of direction provided by the inventor.

The inventor has provided evidence that roxithromycin is effective in inhibiting proliferation of vascular smooth muscle cells.

(D) The existence of working examples.

The working examples are limited to showing that erythromycin is effective in inhibiting proliferation of vascular smooth muscle cells.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict *priori* whether macrolides encompassed by the present claims will be effective in prevention of diseases caused by proliferation of vascular smooth muscle cells and for prevention of re-obstruction, it would take a large amount of experimentation to determine the effectiveness of said macrolides in preventive therapy.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by the Japanese Patent No. 11-209290.

The Japanese Patent discloses the claimed composition comprising roxithromycin.

The Japanese Patent also teach administration of roxithromycin to patients with myocardial infraction. The inhibition of the proliferation of vascular smooth mudcles would have been inherent from such as administration

Claims 1-3, 5, 6, 8-11, 13-17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shor et al (U.S. Patent No. 5,830,874).

Shor et al disclose the claimed composition comprising erythromycin and a method of treating arterial restriction with erythromycin (column 3, lines 1-2). The inhibition of the proliferation of smooth muscle cells would have been inherent from such an administration.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shor et al (U.S. Patent No. 5,830,874).

Shor et al disclose a method of treating arterial restriction with erythromycin (column 3, lines 1-22). A person having ordinary skill in the art at the time the claimed invention was made would have been motivated to use erythromycin in order to prevent re-obstruction of a coronary artery after the operation of obstruction in cardiac artery since erythromycin is known to be useful in treating nonacute arterial restriction as disclosed by Shor et al.

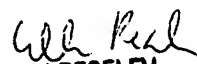
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev


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